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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,396	02/22/2002	Junichi Miyazaki	2002-0053	2281

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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,396	MIYAZAKI ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This paper is in response to paper filed November 8, 2004.

Claims 1- 4, and 9- 11 are under consideration in this action.

Claim Objections Withdrawn

The objections to claims 1, 4, and 9 are withdrawn.

Applicant has amended the claims to render the objections moot.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1- 4 and 9- 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Applicant has amended the claims and the rejection is moot.

Claim Rejections - 35 USC § 103

The rejection of claims 1- 4 and 9- 11 under 35 U.S.C. 103(a) as being unpatentable over Kojima *et al.* (Biochem. Biophys. Res. Com., 1998, Vol 246, pages 868- 872, from IDS), Chen *et al.* (Somatic Cell and Molecular Genetics, 1996, Vol. 22,

Art Unit: 1648

pages 477- 488, from IDS), and Snaith *et al.* (Gene 1995, Vol 166, pages 173- 174, from IDS) is withdrawn.

Applicant has amended the claims and explained how the claimed structure is not obvious over the cited art.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 112

Claims 1- 4 and 9- 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the metes and bounds of the term “outer sequence” in claims 1 and 9 is. Applicant points to the specification and a figure but this does not define what the limits of the term is other than a restriction site.

Claims 1 and 9 are also not clear as to what is meant by “deletion....or E1 and E3 regions” is everything deleted between E1 and E3 or is there more than one deletion with an insertion?.

Claim Rejections - 35 USC § 103

Claims 1- 4 and 9- 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham (EMBO 1984 Vol 3, pages 2917-2922), Fu *et al.* (from IDS), and Chen *et al.* (previously cited).

Art Unit: 1648

The claims are drawn to a method to make an adenovirus vector with an E1 and or E3 deletion and inserted into the deletion a sequence comprising a cosmid, linker, and recombinase site and a vector that comprises those elements.

Graham teaches the invention essentially as claimed.

Graham teaches a plasmid based vector that can be used to make an infectious adenovirus with an E1 deletion (Figure 1). Graham teaches that plasmids are more efficient for manipulating adenovirus than live virus but there may be stability problems (page 2921, last paragraph).

Graham does not teach cosmids or recombinase sites.

Fu et al. teach that cosmids are able to handle the large size of adenoviral DNA, and that they work in bacteria (page 1322, column 1 last paragraph to last paragraph on same page).

Chen *et al.* teach that recombination systems (Cre-lox) have been extensively used for the manipulation of DNA (page 477 first paragraph).

One of skill in the art at the time of invention would have known that cosmids could be used as a "plasmid" to carry a large insert. One of ordinary skill in the art would have been motivated to modify the plasmid of Graham because of the strength of the cosmid system as taught by Fu *et al.* One of ordinary skill in the art at the time of invention would know about E1 and E3 deletion and insertions into the region for expression because that is well known in the art.

One of skill in the art at the time of invention would have known that the extra cosmid sequences are not required in the adenoviral vector and that the sequence can

Art Unit: 1648

be removed leaving only the sequence to be expressed and thus making vectors like the ones known in the art to be used (a vector with an E1 and or E3 deletion and an expressed heterologous sequence inserted in the region of the deletion by means of an expression cassette).

Thus, it would have been *prima facie* obvious to modify the vector of Graham with the cosmid and recombinase to make the vector as claimed with the expectation of success in making an adenoviral vector with an expression cassette inserted into a deletion of the E1 and or the E3 region.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Myron G. Hill

Patent Examiner

January 21, 2005

